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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,257	06/12/2001	Sachiko Yamamoto	70281/55,986	4822

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EXAMINER	
FRONDA, CHRISTIAN L	
ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 01/29/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/879,257	Yamamoto et al.
Examiner	**Art Unit**
Christian L. Fronda	1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____ .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-46 is/are pending in the application.

4a) Of the above, claim(s) 1-13 and 20-46 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 14-19 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Applicants' election with traverse of Group VI, claims 14-19 and SEQ ID NO: 6, in Paper No. 9 is acknowledged. Applicants' position is that the inventions would have overlapping searches and that the claims can be searched without serious burden on the Examiner. This is not found persuasive. A search of all the inventions in the patent literature and the non-patent literature cannot be made without serious burden because the inventions require separate searches that have different limits, boundaries, scope, and subject matter. Because these inventions are distinct for the reasons of record and have acquired a separate status in the art as shown by their divergent subject matter and classification, restriction for examination purposes is proper. The requirement is still deemed proper and is therefore made FINAL.

2. Claims 14-19 and SEQ ID NO: 6 are under consideration in this Office Action.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 14-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to any hybrid enzyme of any amino acid sequence and structure having any enzymatic activity in which any peptide is inserted at any position of the amino acid sequence of any glucose-6-phosphate dehydrogenase (G6PDH) of any amino acid sequence, wherein when said peptide binds to any material having binding ability to the peptide the activity of any glucose-6-phosphate dehydrogenase is then modulated. The specification, however, only provides the following representative species encompassed by these claims in Table 2, specifically, modified G6PDH enzymes designated as Asp294/Ser295, Leu305/Asp306, Asp306/Val307, Pro308/Ala309, Ala309/Asp310, Glu362/Gln363, and C-terminal, in which a

peptide of amino acid sequence SEQ ID NO: 2 is inserted at the designated position of a G6PDH enzyme consisting of the amino acid sequence of SEQ ID NO: 6.

There is no written description of any other hybrid enzyme of any amino acid sequence and structure having any enzymatic activity in which any peptide is inserted at any position of the amino acid sequence of any glucose-6-phosphate dehydrogenase (G6PDH) of any amino acid sequence, wherein when said peptide binds to any material having binding ability to the peptide the activity of any glucose-6-phosphate dehydrogenase is then modulated. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

5. Claims 14-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for modified G6PDH enzymes listed in Table 2 of the specification, specifically, modified G6PDH enzymes designated as Asp294/Ser295, Leu305/Asp306, Asp306/Val307, Pro308/Ala309, Ala309/Asp310, Glu362/Gln363, and C-terminal, in which a peptide of amino acid sequence SEQ ID NO: 2 is inserted at the designated position of a G6PDH enzyme consisting of the amino acid sequence of SEQ ID NO: 6; does not reasonably provide enablement for any other embodiment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of claims encompass any hybrid enzyme of any amino acid sequence and structure having any enzymatic activity in which any peptide is inserted at any position of the amino acid sequence of any glucose-6-phosphate dehydrogenase (G6PDH) of any amino acid sequence, wherein when said peptide binds to any material having binding ability to the peptide the activity of any glucose-6-phosphate dehydrogenase is then modulated. The specification provides guidance and examples for making modified G6PDH enzymes as shown in Table 2, specifically, modified G6PDH enzymes designated as Asp294/Ser295, Leu305/Asp306, Asp306/Val307, Pro308/Ala309, Ala309/Asp310, Glu362/Gln363, and C-terminal, in which a peptide of amino acid sequence SEQ ID NO: 2 is inserted at the designated position of a G6PDH enzyme consisting of the amino acid sequence of SEQ ID NO: 6.

While molecular biological techniques and genetic manipulation techniques are known in

the prior art and the skill of the artisan are well developed, knowledge regarding the specific amino acid sequence of any hybrid enzyme of any amino acid sequence and structure having any enzymatic activity in which any peptide is inserted at any position of the amino acid sequence of any glucose-6-phosphate dehydrogenase (G6PDH) of any amino acid sequence, wherein when said peptide binds to any material having binding ability to the peptide the activity of any glucose-6-phosphate dehydrogenase is then modulated, and the amino acid sequence of any said peptide to be inserted in any position is lacking. Thus, searching for the amino acid sequence of the hybrid enzyme claimed is well outside the realm of routine experimentation and predictability in the art of success is extremely low.

The amount of experimentation to make the invention is enormous and encompasses obtaining any G6PD of any amino acid sequence from any biological source and any peptide of any amino acid sequence, inserting the peptide in any position, and then determining whether G6PDH activity is modulated when said peptide binds to any material having binding ability to the peptide. Since routine experimentation in the art does not include such experimentation where the expectation of obtaining the specific amino acid sequence of the claimed invention is unpredictable, the Examiner finds that one skilled in the art would require additional guidance, such as information regarding the structure and amino acid sequence of the claimed hybrid enzyme. Without such a guidance, the experimentation left to those skilled in the art is undue.

Conclusion

6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. The Examiner can be contacted Monday-Friday from 8:30AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF

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